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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,341	04/13/2000	ERIC GORDON MAHERS	602-1466	4968

7590 07/18/2003

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[REDACTED] EXAMINER

MILLER, MARTIN E

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

2623

DATE MAILED: 07/18/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/462,341	MAHERS ET AL.
	Examiner Martin Miller	Art Unit 2623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on amendment filed 4-28-03.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-18 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Amendment

1. The Examiner acknowledges the amendment filed April 28, 2003. Accordingly, claims 6, 13-15, and 18 have been amended. The Examiner withdraws his 35 USC 112, second paragraph rejection of claims 6, 14-18.

Response to Arguments

2. Applicant's arguments filed April 28, 2003 have been fully considered but they are not persuasive. At page 6, fourth paragraph of Applicant's response, Applicant argues that the barcode sensor of Berndt cannot be read by the station, however, if applicant would read the Abstract it clearly states, a barcode is associated with each of the sample vials, and the test station makes a reading of that barcode **concurrent** with the determination being made as to whether there is any bacterial growth in the sample vial. (emphasis added).

At page 6, fifth paragraph of Applicant's response that continues on to page 7, Applicant states, "neither the sensor nor the vial contains antibiotic related to any test", however, the Abstract of Berndt states "A system for detecting the presence of bacteria growth in a plurality of sample vials" and bacterial growth is directly related to determining whether a bacteria is susceptible to an antibiotic. One of ordinary skill in the art would know that detecting bacteria growth would indicate whether an antibody is effective or not against a particular bacteria.

On page 7, applicant argues that sample vials not solid culture plates, however, such a limitation is not present in the claim.

Applicant also argues that barcodes cannot provide orientation information (p. 7, paragraphs 3and 4), however, Berndt specifically states "Preferably, the bar codes and sensors of

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Figs. 8 and 9 are printed on a label such that they are properly positioned relative to each other ." (col. 9, ll. 43-45) and "the image received by camera 190 is stored in the controller's memory and analyzed for the position of the concentric circles 230 or 232 and /or the bar code pattern relative to the center of CCD matrix 244." (col. 10, ll. 13-16). At col. 10, l. 16, Berndt goes on to make corrections based on the perceived position data, so inherently Berndt must be able to ascertain some orientation if the system is going to make corrections.

With respect to applicants arguments that vial is not an AST disk, mere use of an abbreviation does not obviate the functional equivalence of a vial to the disk. In the Amaral reference, US 4416995, it is taught that the container used can be a test tube (col. 8, ll. 3-5) and that such test tubes can be used "ascertain the susceptibility of the bacteria to antibiotics"(col. 5, ll. 64-65).

Applicant also argues that Berndt does not "interpret any region of visibly altered micro-organism growth", however, Berndt teaches that he detects growth based on the imaged sample versus an image of a reference fluorophore (col. 10, ll. 39-43, for more background, see col. 9, ll. 20-30). Therefore, based upon the reference image a determination (interpretation) is made whether the bacteria has grown or not.

With respect to claim 12, applicant argues that because Graessle only teach one way of inserting the carrier that there is no need of an orientation means, however, claim 12 and 17 require the multi-character code to properly aligned not the carrier. Wevelsiep teaches using an underline to properly align a barcode image. Applicant also argues that there is no suggestion that a barcode contain antibiotic information, but it is well known that barcodes can contain any

form of information and a barcode with antibiotic information is not beyond the grasp of one of ordinary skill in the art.

Therefore, the examiner maintains his 35 USC 103(a) rejections of the claims 1-18.

Claim Objections

3. Claim 12 is objected to because of the following informalities: claim 12 recites in the preamble the phrase, "each of which holds a plurality of devices each in accordance with any of the preceding claims", the examiner is uncertain whether the applicant intends this claim to be a multiple dependent claim in which case the proper fees must be charged. Applicant is request in response to this office action to confirm the intent of claim 12 being a multiple dependent claim or amending the claim to a proper independent claim (also correcting any possible lack of antecedence if it is amended). Claim 12 also recites "electronic information processing means, preferably a neural net, ...". Since a neural net is only preferable no weight is given to the limitation of a neural network. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 13-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per claim 13, it now recites an image analysis system that "determines a visible characteristic of the zone of inhibition, if any, surrounding the located device." However, it is the understanding of the Examiner that the zone of inhibition is the area where bacterial growth

has not occurred due to the presence of the antibiotic, but the claim says that the zone surrounds the device. If the antibody is supposed to be in the device how can the zone surround the device? The examiner finds support for his interpretation at page 1, 7-9 lines up from the bottom of the page.

Claims 14-17 are rejected due to their dependence upon rejected claim 13.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-3, 6, 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berndt, US 5595708.

As per claim 1, Berndt teaches:

a carrier device (fig. 7, element 32);

the device releasably carrying an antibiotic (typically vials contain blood being examined for biological activity, col. 3, ll. 43-51) related to the test, and bearing machine readable information (barcode, Abstract) concerning the antibiotic, wherein the device also includes orientation means (CCD camera and the barcodes 234 and 212 of figure 9) image for enabling an image analyzer (col. 9, ll. 39-40, col. 10, ll. 15-29) to determine the optimal reading direction of the readable information. The examiner is interpreting "optimal reading direction" to mean barcode in the proper orientation to be read.

Berndt does not specifically teach that his system is used with an antibiotic susceptibility test (AST), however, it would have been obvious to one of ordinary skill in the art to use sample marking system of Berndt to keep track of biological samples to insure that the determined results of the test are tied to a particular sample and to avoid a misidentification of either the vial or test results. Additionally, Berndt's system assures that the vial will automatically be in the correct reading position for the CCD.

As per claim 2, Berndt teaches:

orientation means comprises means other than said machine readable information (reference indicia, col. 2, ll. 36-40).

As per claim 3, Berndt teaches;

in which the orientation means is separate from said machine readable information (fig. 9 element 234 versus element 212).

As per claim 6, Berndt teaches:

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the orientation means comprises an arrangement of information presented on the device surface (reference indicia fig. 9, element 234), in addition to the readable information (fig. 9, element 212).

As per claim 7, Berndt teaches:

in which said orientation means comprises linearly-arranged information (fig. 9, element 234 comprises linearly arranged information).

As per claim 11, Berndt teaches:

which said machine readable information or character code identifies said substance and/or its concentration (required writing, col. 1, ll. 34-36 and col. 10, ll. 26-30). It would have been obvious to one of ordinary skill in the art that barcodes can contain a large amount of data including and such items as a station numbers and data pertaining to the device at that location.

9. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brendt, further in view of Amaral, US 4416995.

As per claim 5, Berndt does not teach an AST disk; however, Berndt teaches imaging a vial, which is the functional equivalent of an AST disk. Amaral teaches that it is well known to use vials (fig. 2) to test a chemical to ascertain susceptibility of the bacteria to antibiotics (col. 5, l. 62-col. 6, l. 2). Therefore, it would have been obvious to one of ordinary skill in the art to use the imaging system of Berndt, in light of the teaching by Amaral that AST can be performed in vials, that operates upon smaller indicia than what could be placed upon a disk because the greater resolution required of Brendt would easily perform the same function on a larger barcode identifier.

10. Claims 4, 8-10, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brendt, further in view of Wevelsiek et al. (hereinafter Wevelsiek), US 4403339.

As per claim 4, Brendt teaches machine-readable codes not character codes. However, Wevelsiek teaches reading character codes, Wevelsiek teaches:

in which the machine readable information comprises a code of one or more characters (col. 7, ll. 44-46), whereby an image analyzer comprising code reading means, can determine the orientation of the code (col. 8, ll. 9-16, col.)

Brendt teaches:

, using the orientation means, and can adjust the orientation of the code (col. 9, ll. 39-40, col. 10, ll. 14-15), or an image thereof, to bring the perceived orientation into alignment with that necessary for proper reading of the code (col. 10, ll. 27-33).

It would have been obvious to one of ordinary skill in the art to use the character codes, which are human-readable, of Wevelsiek in place of the only machine-readable codes of Brendt so that the user can quickly read the label and verify the location if one of the vials gets mispositioned or misplaced.

As per claim 8, Wevelsiek teaches:

wherein said linearly-arranged information (fig. 2, element 75) is parallel to the optimal reading direction of the readable information (fig. 2, element 70).

As per claim 9, Wevelsiek teaches:

wherein said linearly-arranged information is a printed line or lines, printed below or above the readable information (fig. 2, element 75).

As per claim 10, Wevelsiek teaches:

wherein said orientation means comprises an underline printed beneath the character code (fig. 2, element 75).

As per claim 18, Berndt does not specifically teach a culture medium, but he does teach a blood vial used for detecting the presence of bacterial growth (first sentence of abstract). Berndt teaches:

- a) camera means for viewing the medium (vial) (CCD camera, col. 10, ll. 9-11);
- b) electronic information processing means (system controller, fig. 7, element 98, col. 10, ll. 4-6), linked to said camera (col. 10, ll. 13-16), programmed or trained to interpret any region visibly altered micro-organism growth (bacterial growth) in the vicinity of a susceptibility testing device, such as a disk, present on the culture medium (col. 10, ll. 37-47).

Berndt does not specifically teach reading a character code, but he teaches processing all the information of a machine-readable code. Therefore, with respect to a machine-readable code, Berndt teaches:

wherein said processing means is also programmed or trained to read a code on the device indicative of the susceptibility reagent in the device and to interpret orientation means incorporated in or on the device by which optimal reading direction of the code can be recognized, and to adjust as necessary the actual reading direction to bring this into line with the actual orientation of the code on the device (col. 10, ll. 14-17).

With respect to determining the orientation of a character code, Wevelslep cures the deficiency of Berndt by using character codes as his machine-readable indicia (fig. 2, element 71). It would have been obvious to one of ordinary skill in the art to use the character code of Wevelslep to label a vial to improve the labeling security of Brendt by using a code that is

human-readable so that if a vial does get mispositioned it can be easily identified by a user.

Additionally, the user would not have to use a barcode scanner to determine where the vial should go in the device.

11. Claims 12, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Graessle et al., (Hereinafter Graessle), US 5573950 and Tsuchiya et al., (hereinafter Tsuchiya), US 5134272.

As per claim 12, neither Graessle nor Tsuchiya does not specifically teach an AST plate; however, Graessle teaches using a disposable microorganism culturing device (col. 5, ll. 18-21) which is equivalent to a AST. Therefore Graessle teaches:

Support means for supporting an AST plate (fig. 2, cassette 20, col. 4, ll. 60-65); camera means for imaging a plate supported by said support means (CCD image sensor, col. 8, ll. 5-7); and

electronic information processing means, preferably a neural net, linked to said camera means(microprocessor, col. 8, l. 5-7), programmed or trained to locate ("incrementally advance substrates through the imaging position", col. 8, ll. 18-20) an AST carrier device on said plate from among the plurality of AST carrier devices,

However, Graessle does not teach aligning the perceived barcode image into the proper alignment. But, Tsuchiya teaches:

identify orientation means on the located carrier device (fig. 2a) , and rotate (Tsuchiya teaches that he derives a position coordinate representing a central axis and a center position, col. 2, l. 67-col. 3, l. 5) the perceived image of the located device as required so that the perceived image of the located device as required so that the perceived image of a multi-character (fig.

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2(a), element A, shows multi-character code) code printed on the device is brought into alignment (decoding is done on the pixel values extending along the determined central axes, col. 3, ll. 7-8) with a proper reading direction for the code, and reading the code (col. 3, ll. 5-10).

It would have been obvious to one of ordinary skill in the art to use the image processing features of Tsuchiya to correct for misaligned barcode images so that the system does not have to be manually adjusted or mechanically adjusted for the barcode to be decoded in the automated scanning system of Graessle.

As per claim 13, Tsuchiya teaches:

a visible characteristic of the zone of inhibition, if any, surrounding the disk (fig. 2d, because the specification states that the inhibition zone is the darkest part of the image, p. 13, ll. 15-20). Since there is a lack of antecedent basis for the disk, the examiner is interpreting the disk to be the multi-character code.

As per claim 15, Graessle teaches:

displaying means for displaying the disk image (col. 8, ll. 40-43). The CCD image is provided to a computer it is well known that a monitor connected to the computer can then display such imagery. This would have been obvious to one of ordinary skill in the art.

As per claim 16, Tsuchiya teaches:

wherein the diameter of the zone of inhibition is determined (col. 7, ll. 49-53). Tsuchiya teaches that the center coordinates of the black region is determined, it would have been obvious to one of ordinary skill in the art to divide the diameter by 2 to determine the center position of the black region.

12. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Graessle and Tsuchiya, further in view of Rutenberg, US 4965725.

As per claim 14, Graessle teaches:

wherein the electronic information processing means includes or is linked (col. 8, ll. 42-44) to a database for analysis. But neither Graessle nor Tsuchiya teach an expert system.

However, Rutenberg teaches:

an expert system comprising a database of AST characteristics of known organisms (col. 1, ll. 46-49).

It would have been obvious to one of ordinary skill in the art to use a expert system to analyze the image pattern provided by Graessle to combine the experience of a human technologist and trainable artificial intelligence.

13. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Graessle and Tsuchiya, further in view of Wevelsiek.

As per claim 17, neither Graessle nor Tsuchiya teaches an underline beneath the multi-character code. However, Wevelsiek teaches:

wherein the system is programmed or trained to identify orientation means which comprises an underline printed beneath the multi-character code (fig. 2, element 75). It would have been obvious to one of ordinary skill in the art to use the underline of Wevelsiek in the imaging system of Graessle and Tsuchiya to provide an additional means to insure the proper alignment of the code being read by Tsuchiya and Graessle.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following U.S. patent(s) refer(s) to AST testing: Ericsson et al., 5639632, Braier et al., 5694478, Staples, 5766553 and 6045758, Peck et al., 5789173, Chen et al., 5916812, Wardlaw, 6022734 and 6140069, Clark et al., 6096272.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martin Miller whose telephone number is (703) 306-9134. The examiner can normally be reached on Monday-Friday, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amelia Au can be reached on (703) 308-6604. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9314 for regular communications and (703) 872-9314 for After Final communications.

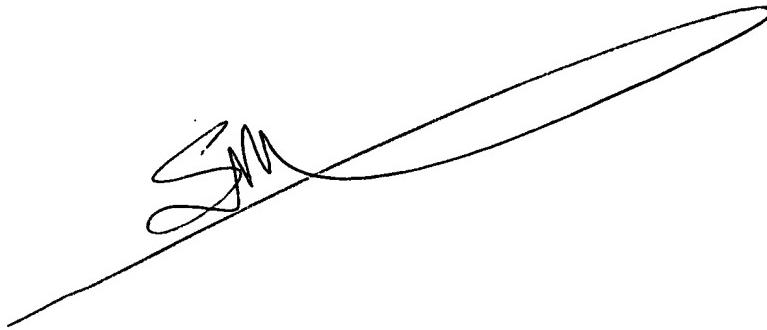
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3900.

SAMIR AHMED

mem

July 12, 2003

A handwritten signature in black ink, appearing to read "SAMIR AHMED", is written over a diagonal line that extends from the bottom left towards the top right of the frame.

**SAMIR AHMED
PRIMARY EXAMINER**